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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,316	07/17/2003	Robert W. Childers	DI-5766	3437

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EXAMINER	
CHAPMAN, GINGER T	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,316	CHILDERS ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *27-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-61 are pending in the application, claims 27-61 are withdrawn by way of Applicants amendment filed 4 April 2007.

Withdrawn objections:

The objections to the drawings made of record in the previous Office action are withdrawn in view of Applicants' amendment to the drawing and in view of Applicants clarification that the sorbent cartridge (32) described on page 16 of the Specification is the claimed medical fluid regenerator.

The objection to claim 16 made of record in the previous Office action is withdrawn in view of Applicants' amendment to the claim.

Drawings

The drawings were received on 4 April 2007. These drawings are acceptable.

Response to Arguments

Applicant's arguments, see Remarks, page 12, regarding the "medical fluid regenerator", filed 4 April 2007, with respect to the rejection of claim 1 under 35 USC 102(b) have been fully considered and are persuasive. In particular, Applicant has clarified that the claimed medical

fluid regenerator is the sorbent cartridge (32) depicted in figure 1 and described at page 16, l. 7 to page 17, l. 29.

Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made in view of Karoor et al (US 2003/0105424 A1).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al (US 2001/0041892 A1).

With regard to claim 1, as seen in Figure 1, Burbank et al teach a system for providing dialysis [0065] comprising a patient fluid loop (14) including a first pump (20) and multiple patient lumens (16, 30); a second fluid loop (80) including a second pump (96) and a medical fluid regenerator (82); a membrane device (52) in fluid contact with and separating the patient fluid loop (14) and the second fluid loop (48), the membrane device (52) allowing at least one selected component of the fluid in the patient fluid loop to transfer to the second fluid loop [0058]; the second loop (48) being closed except for the transfer of the selected component via the membrane device (fig. 1); and a controller (98) that operates the first and second pumps to recirculate fluid in the patient loop and the second loop [0056].

With regard to claim 2, Burbank discloses the membrane device (22) is a dialyzer ([0052, 65].

With regard to claim 3, Burbank discloses a pressure gradient exists across the membrane device [0052].

With regard to claim 4, Burbank discloses the patient loop (14) is closed except for the transfer of the selected component via the membrane device [0059].

With regard to claim 11, Burbank teaches the second fluid loop (48) includes a multi-analyte sensor (100, 70) [0056].

With regard to claim 12, Burbank teaches peritoneal dialysis fluid is circulated through the patient fluid loop [0065].

With regard to claim 13, Burbank teaches blood is circulated through the patient fluid loop [0051].

With regard to claim 14, Burbank discloses at least parts of the patient fluid loop (216) and the second fluid loop (192) are provided in a disposable device [0079].

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al in view of Karoor et al (US 2003/0105424 A1).

With regard to claim 5, Burbank discloses the membrane device (52) includes a hyperfilter (50) but does not explicitly disclose a nanofilter which allows urea to pass from the patient fluid loop to the second fluid loop. Karoor et al, at at [0005], expresses the desire for a

dialysis system that removes toxins from a patient. As seen in Figure 1, Karoor teaches a dialysis system comprising a patient fluid loop (11) and a second fluid loop (12) including a membrane device (20) that includes a filter which allows urea to pass from the patient fluid loop to the second fluid loop [0071] for dialysis thereby the filter of Karoor performs the identical function of allowing urea to pass as the claimed nanofilter. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the dialysis system of Burbank comprising a nanofilter as taught by Karoor in order to provide a dialysis system that removes toxins from the blood of a patient.

With regard to claim 6, Burbank discloses a sorbent [0063; 0052 (46)] but does not explicitly disclose a uremic toxin sorbent. Karoor, at [0005], expresses the desire for a dialysis system including a uremic toxin sorbent. As seen in Figure 2, Karoor teaches a medical fluid regenerator (32) including a uremic toxic sorbent [0073]. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Burbank comprising a uremic toxin sorbent as taught by Karoor in order to remove urea from a dialysis patient's blood.

With regard to claim 7, Karoor teaches urease [0080].

With regard to claim 8, Karoor teaches a gas separator (52) that removes gas from the second fluid loop.

With regard to claim 9, Karoor teaches the gas separator (52) and the medical fluid regenerator (32) are provided in a single device [0076].

With regard to claim 10, Karoor teaches a gas vent (54).

Claims 15, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank in view of Polaschegg (US 5,522,998).

With regard to claim 15, Burbank discloses the claimed invention except for a balance chamber. Polaschegg, at c. 2, ll. 3-15, expresses the desire for dialysis systems to comprise balance chambers in order to achieve a steady and constant flow of dialysis fluid. As seen in Figure 1, Polaschegg teaches a dialysis system comprising a patient loop (20) and a second fluid loop (40) and a balance chamber (30) that balances flow within the second fluid loop (40). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Burbank including a balance chamber as taught by Polaschegg since Polaschegg states at c. 2, ll. 3-4 and at c. 8, ll. 17, that the benefit of forming the system with this design is that it achieves steady and constant flow of dialysis fluid thereby providing a more efficient dialysis system.

With regard to claim 24, Polaschegg discloses an ultrafiltrate container (54) in fluid communication with second fluid loop (40).

With regard to claim 25, Polaschegg discloses a fluid concentrate container (42) in fluid communication with the second fluid loop (40).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank in view of Geary et al (US 4,950,259).

With regard to claim 17, Burbank discloses the invention substantially as claimed but does not expressly disclose a dual lumen catheter. Burbank, at [0051] teaches the ability of the dialysis system to be connected to the vasculature of a patient thus expressing the desire for such.

Geary et al, at c. 1, ll. 45-68 expresses the desire for a catheter comprising more than a single lumen to increase the efficiency of peritoneal dialysis. As seen in Figures 1-3, Geary et al teach a dual lumen catheter (8) for use with a system for providing dialysis. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the connection of Burbank comprising a dual lumen catheter as taught by Geary since Geary states at c. 8, ll. 47-60 and c. 9, ll. 10-20 that the advantage of using such a dual lumen catheter is that it maintains a greater solute concentration and osmotic gradient over that of a single lumen catheter and permits continuous flushing thereby providing greater dialysis efficiency.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank in view of Savitz et al (US 4,229,299).

With regard to claim 18, Burbank discloses the claimed invention but does not explicity disclose a heater. Savitz, at c. 12, ll. 30-35, teaches that the fluid in the dialysis system must be maintained at approximately normal body temperature to preclude undue heating or cooling of the blood by heat transfer in the dialyzer. As seen in Figure 3, Savitz teaches a dialysis system including at least one of the patient fluid loop (C) and the second fluid loop (B) includes an in-line fluid heater (103,152). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Burbank comprising heaters since Savitz teaches the benefit of maintaining the fluid at normal body temperature thereby providing a safer dialysis system.

With regard to claim 19, the combination of Polaschegg and Savitz discloses heaters (see claim 18, *supra*) but does not expressly disclose a radiant heater and a plate heater. Savitz, at c.

12, ll. 28-29 teaches that the heaters can be of any suitable conventional type of heater and at c. 6, ll. 5-35 that such heating is carried out for the purpose of maintaining the fluid at a proper temperature to prevent undue heating or cooling of the blood and to prevent hemolysis. In view of the teachings of Savitz, it would have been obvious to one having ordinary skill in the art at the time the invention was made that the heaters disclosed by Savitz are fully capable of comprising radiant or plate heaters because Savitz states at c. 12, ll. 28-29 that any suitable conventional heater may be used, therefore these heaters are equivalent for the desired purpose of maintaining proper temperature; two equivalents are interchangeable for their desired function, express suggestion of substitution not needed to render such substitution obvious. *In re Siebentritt*, 54 CCPA 1083.

With regard.to claim 20, Savitz discloses a multi-analyte sensor (105) that monitors a concentration of electrolytes, e.g. ammonium, in the medical fluid (c. 6, ll. 40-55).

Claims 16, 21-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank ('892) in view of Burbank et al (US 6,579,253 B1).

With regard to claim 16, Burbank discloses the invention substantially as claimed but does not expressly disclose the controller enables fluid flow in opposite directions through the multiple patient lumens. Burbank ('253), at c. 10, ll. 37-38 expresses the desire to enable fluid to flow in opposite directions through the patient lumens to rinse back blood to the patient. As seen in Figures 1 and 11, Burbank ('253) teaches a system (fig. 1) for providing dialysis comprising a patient fluid loop (62) and a second fluid loop (68) and controller (22) enabling fluid to flow in opposite directions through the patient lumens (c. 21, ll. 25-38). Therefore it would have been

obvious to one having ordinary skill in the art at the time the invention was made that the controller of Burbank ('892) enable fluid to flow in opposite as taught by Burbank ('253) since Burbank ('253) states at c. 21, ll. 35-38 that the benefit of operating the system in this mode is that it returns fluid to a patient in a bolus volume, e.g. during a hypotensive episode or during rinse back at the end of a dialysis treatment session.

With regard to claims 21, 22 and 23, Burbank ('253) discloses a fluid volume sensor (182) in at least one of the patient and second fluid loops (68); the sensors can be, *inter alia*, capacitance sensors (c. 23, ll. 35-40; c. 11, l. 48) that use a pump chamber (214) in fluid communication with the loop (68).

With regard to claim 26, Burbank ('253) discloses the controller operates the pump (144) continuously to pump fluid into and out of a patient (c. 7, ll. 7-8; c. 21, ll. 3-9).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 5-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 59-60 of copending Application No. 09/990,673. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims every limitation of the claimed invention except for the patient fluid loop and controller. It is widely known in the dialysis art to provide a patient fluid loop and a controller in dialysis systems.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The examiner notes that on 7 March 2007 a notice of allowance was issued for copending Application No. 09/990,673 and on 1 June 2007the issue fee payment was verified.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gigou et al (US 3,926,797) teaches a patient fluid loop (12) and a medical fluid regeneration loop (21).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
06/08/07

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SUPERVISORY PRIMARY EXAMINER